

INSTRUCTIONS FOR USE



■ Epower™ Microorganisms

INTENDED USE

Epower™ Microorganisms are lyophilized, quantitative microorganism preparations to be used in industrial laboratories for quality control purposes. A single **Epower™ Microorganisms** can be employed as an individual microorganism challenge or several **Epower™ Microorganisms** can be combined and employed as a mixed microorganism population challenge. These microorganism preparations are traceable to the America Type Culture Collection (ATCC®) or other authentic reference culture collection.

FORMULA COMPONENTS

The lyophilized preparation consists of an enumerated microorganism population, skim milk (bovine - USA origin), a carbohydrate, gelatin (porcine - USA or Canada origin), ascorbic acid, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and a carbohydrate protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

Epower™ Microorganisms conform with Article 5 of EC 1069/2009 as they have reached the end point in the manufacturing chain and are no longer subject to the requirements of EC 1069/2009.

The products are considered derived products per Article 36 of EC 1069/2009 and do not pose any significant risk to public or animal health.

SPECIFICATIONS AND PERFORMANCE

Epower microorganisms are packaged in a kit configuration. Each kit consists of:

- 1 vial containing 10 lyophilized pellets of an individual microorganism strain
- Instructions for Use

Epower microorganisms are available at a variety of challenge concentrations. These concentrations are identified by the code at the end of the catalog number.

For Example:

Catalog number 0392E3 identifies a challenge concentration of 10^3 CFU per pellet. This means each E3 pellet will contain 1,000 – 9,999 CFU.

Catalog number 0392E6 identifies a challenge concentration of 10^6 CFU per pellet. This means each E6 pellet will contain 1,000,000 – 9,999,999 CFU.

Pellet Concentration	Examples of Concentration (CFU/ml) in Specified Hydration Fluid Volume		
	1 ml	10 ml	100 ml
E2	100 – 999	10 – 99	1 – 9
E3	1,000 – 9,999	100 – 999	10 – 99
E4	10,000 – 99,999	1,000 – 9,999	100 – 999
E6	1,000,000 – 9,999,999	100,000 – 999,999	10,000 – 99,999
E7	10,000,000 – 99,999,999	1,000,000 – 9,999,999	100,000 – 999,999
E8	100,000,000 – 999,999,999	10,000,000 – 99,999,999	1,000,000 – 9,999,999



Quality control documentation includes, but is not limited to, an online Certificate of Analysis stating:

- The identity of the microorganism
- The traceability of the microorganism to a reference culture
- That the microorganism preparation is ≤ 3 passages from the reference culture
- The mean assay value for the microorganism preparation

Microbiologics Recommended Growth Requirements Technical Information Bulletin (TIB.081) lists the recommended media and incubation requirements for strains. This TIB, along with many others, are available on our website.

INSTRUCTIONS FOR USE

1. Remove the vial of pellets from refrigerated storage and allow to equilibrate to room temperature (about 30 minutes).
2. Prior to use, warm hydration and dilution fluids to 34°C–38°C. Sterile pH 7.2 phosphate buffer is recommended for hydration of the lyophilized preparation.
3. With sterile forceps, transfer the microorganism pellet(s) to the hydration fluid. Do not remove the desiccant from vial. Immediately stopper and recap the vial and return to 2°C–8°C.
4. Place the microorganism suspension into a 34°C–38°C incubator for 30 minutes to assure complete hydration.
5. Immediately following incubation, vortex hydrated material until a homogeneous suspension is achieved. Charcoal particles, which may be visible in the hydrated suspension, will not compromise the challenge microorganism.
6. Proceed with the challenge according to laboratory protocol. The challenge must be completed within 30 minutes of the hydration process to avoid a change in the challenge suspension concentration.

PRECAUTIONS AND LIMITATIONS

- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- **Epower™ Microorganisms** do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Refer to the SDS for more detailed information. The SDS can be located on our website at www.microbiologics.com or by contacting Technical Support at 320.229.7045.
- These products, and growth of these microorganisms, are considered biohazard material.
- These products contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.
- The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material.
- Only trained laboratory personnel should use these products.
- Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials.
- **Epower™ Microorganisms** are not made with natural rubber latex.

TECHNICAL NOTES

Mean Assay Value

- The mean assay value obtained at Microbiologics® was calculated using well proven statistical methods. As part of Microbiologics' quality control procedure, pellets from each **Epower™ Microorganism** lot are hydrated in Microbiologics Hydrating Fluid. Replicate colony counts are performed on non-selective agar media and enumerated using an automated colony counting device. Results may differ from the assigned mean due to different materials, growth conditions, and methods used.
- Variability of hydration fluid, sampling, different colony counting techniques, incubation and the use of selective agar media will produce colony counts that vary from the stated mean assay value.

Shelf Life and Stability

- Exposure to heat, moisture, and oxygen can adversely affect the stability of the microorganism. Both reproducibility and stability are predicated on proper storage of the lyophilized preparations in the original desiccant-containing vial.
- Hydration activates the respiration and metabolic activity of the lyophilized microorganism. In the absence of critical growth requirements (i.e. nutrients and incubation conditions), the stability of the microorganism population can be affected.

Analyte Challenge

- If the application requires a food sample, do not add the food sample to the hydrated suspension until immediately before processing and testing.
- The potential exposure of moisture and oxygen in the food sample can have a profound influence on the stability of the microorganisms.
- Food samples can also introduce inhibitory or toxic properties that adversely influence the recovery of microorganism populations.
- A food sample can also introduce an intrinsic population of microorganisms which can produce an inhibitory or toxic influence on the remaining microorganisms in the population.

Hydration

- Lyophilized microorganisms must be hydrated to achieve viability. The intrinsic properties of hydration fluids can influence recovery and anticipated assay values.
- The structure of the lyophilized pellet is provided by gelatin, which liquefies when warmed. To liquefy the gelatin, and ensure complete hydration and a uniform suspension of the microorganism population, follow the Instructions for Use.

STORAGE AND EXPIRATION

Store **Epower™ Microorganisms** at 2°C–8°C in the original, sealed vial. Stored as directed, the lyophilized microorganism preparation is warranted to retain, until the expiration date stated on the product label, its specifications and performance within the stated limits.

Epower™ Microorganisms should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

- **Sterile forceps or tweezers**– required for the removal of an individual pellet and placement into the primary dilution fluid.
- **Enrichment broths, dilution fluids, and required testing materials**– for qualitative or quantitative test methods in accordance with each individual laboratory's SOP.

KEY OF SYMBOLS



Batch Code (Lot)



Consult instructions for use or consult electronic instructions for use



Biological Risks



Manufacturer



Catalog Number



Temperature Limitation



Caution, Consult Accompanying Documents; Attention, see instructions for use



Use By

* Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

These products are warranted to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when:

- The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature

If the resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE

Visit our website, www.microbiologics.com, for current technical information, product availability, biohazard cleanup, growth requirements, and Certificate of Analysis.

ACKNOWLEDGEMENTS



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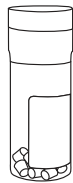
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ILLUSTRATED INSTRUCTIONS

Epower™ Microorganism kits include 1 vial of a single enumerated microorganism (10 lyophilized pellets per vial) and Instructions for Use. If using the Membrane Filtration Method for water testing, please refer to the Illustrated Instructions (LIT.248) located at www.microbiologics.com.

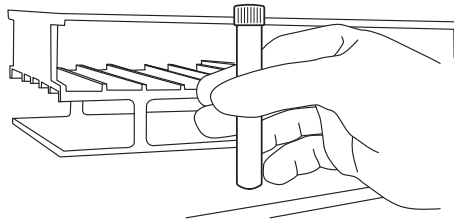
1



Remove the vial of lyophilized pellets from refrigerated storage. Allow the unopened vial to equilibrate to room temperature (about 30 minutes).

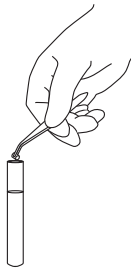
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Prior to use, warm hydration and dilution fluids to 34°C–38°C. Sterile pH 7.2 phosphate buffer is recommended for hydration of the lyophilized preparation.



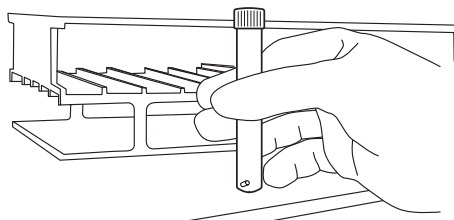
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With sterile forceps, transfer the microorganism pellet(s) to the hydration fluid. Do not remove the desiccant from vial. Immediately stopper and recap the vial and return to 2°C–8°C.



4

Place the microorganism suspension into a 34°C–38°C incubator for 30 minutes to assure complete hydration.



5

Immediately following incubation, vortex hydrated material until a homogeneous suspension is achieved.

Charcoal particles, which may be visible in the hydrated suspension, will not compromise the challenge microorganism.



6

Proceed with the challenge according to laboratory protocol. The challenge must be completed within 30 minutes of the hydration process to avoid a change in the challenge suspension concentration.

